

## **REMARKS**

With entry of the present amendments, claims 1-38, 49-51, and 53-58, are currently pending in the application. Claims 67 and 69-71 are canceled. Claims 1, 9, 18, 28-30, 36, 49, and 53 are currently amended. No new matter has been added by way of amendment. Support for the amendments may be found at least at paragraphs [0018], [0034], [0041] and [0047] of the application as originally filed.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **I. Specification**

The Office has requested that “tetarome” be capitalized in the application and be accompanied by generic terminology. Applicant has done so at paragraphs [0014] and [0045], and requests that this objection be withdrawn.

### **II. Claim Rejections – 35 U.S.C § 112 – 2<sup>nd</sup> paragraph**

Claims 1-38, 49-51, 53-58, 67, and 69-71 stand rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph for allegedly being indefinite. Specifically, the Office has requested that the first use of any of the abbreviations in the claims be preceded by the full meaning of the abbreviated term. Claims 1, 9, 36, 49, and 53 have been amended to delete the abbreviations or define them as requested. Therefore, Applicant requests that this ground of rejection be withdrawn.

Claims 18-19 also stand rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph for allegedly being indefinite. Specifically, the Office has rejected these claims for reciting the trademark “tetarome.” Applicant has deleted "tetarome" and inserted the generic terminology as requested by the Examiner. Withdrawal of this rejection is respectfully requested.

### **III. Claim Rejections – 35 U.S.C. § 112 – 1<sup>st</sup> paragraph**

#### **A. Written Description Rejection**

Claims 1-29, 31-38, 49-51, and 53-58 stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph for allegedly failing to comply with the written description requirement. In support of this rejection, the Office asserts that “nowhere do Applicants distinguish between cancers that express the particular receptor tyrosine kinases recited in the instant claims or provide any means to determine whether a cancer comprises cells expressing PDGFR, c-Kit, or FLT-3.” Office Action, p. 5. Applicant traverses this rejection.

While Applicant vigorously disagrees with the basis of the written description rejection, the present amendment has deleted the language cited by the Office as allegedly lacking support in favor of reciting specific cancers: gastrointestinal stromal cancer, glioma, melanoma, bladder cancer and renal cancer. Since, paragraphs [0018] and [0047] in the specification expressly support the new claim language, this rejection is rendered moot. Accordingly, Applicants respectfully request that the present ground of rejection be withdrawn.

#### **B. Enablement Rejection**

Claims 1-38, 49-51, 53-58, 67, and 69-71 stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph for allegedly failing to comply with the enablement requirement. The Office agrees that the claims are enabled for “‘treating’ cancer to the extent that treating refers to alleviating the symptoms associated with cancer or halting the further progression or worsening of symptoms of cancer.” Office Action, p. 6. However, the Office asserts that the claims are not enabled for “‘treating’ cancer to the extent that treating refers to prevention or prophylaxis of cancer.” *Id.*

Although Applicants believe that the claims are enabled for the meaning of “treating” as defined in paragraph [0041] of the application, solely to expedite prosecution, Applicants have amended independent claims 1, 9, 36, 49, and 53 to recite methods of “alleviating the symptoms of, or halting the progression or worsening of the symptoms of” the cancers recited therein.

Because the Office has agreed that such claims are enabled, Applicants respectfully request that the present ground of rejection be withdrawn.

#### **IV. Claim Rejections – 35 U.S.C. § 103**

Claims 1-6, 9-13, 17, 19-30, 35-38, 49, 53-58, 68, and 69-71 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over U.S. Pat. No. 6,605,617 issued to Renhowe et al. (“Renhowe”) and Foekens et al. Cancer Res., 2001, 61, 5407-14 (“Foekens”) in view of “Guideline for the Format and Content of the Human Pharmacokinetic and Bioavailability Section of an Application” published by the FDA (“FDA Guidelines”). Claims 7-8, and 14-15 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Renhowe and Foekens in view of the FDA Guidelines and in further view of Berge et al., J. Pharm. Sci., 1977, 66, 1-19 (“Berge”). Claims 16 and 18 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Renhowe and Foekens in view of the FDA Guidelines and in further view of U.S. Pat. Pub. No. 20030159702 by Lindell et al. (“Lindell”). Claims 31-34 and 50-51 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Renhowe and Foekens in view of the FDA Guidelines and in further view of the Cecil Textbook of Medicine, 21<sup>st</sup> Ed., Vol. 1, 2000, eds. Goldman and Bennett, p. 1060-1074 (“Cecil”). Applicant respectfully traverses this rejection.

The claims as amended recite methods of alleviating the symptoms of, or halting the progression or worsening of the symptoms of a cancer selected from gastrointestinal stromal cancer, glioma, melanoma, bladder cancer and renal cancer. None of the cited references teaches the use of the present compounds at the present blood levels for treatment of such cancers. Nor has the Office explained why the skilled artisan would modify the prior art methods with a reasonable expectation of success to treat the cancers recited in the present claims. Thus, the cited references do not teach or suggest all the elements of the claimed methods, and the Office has failed to establish a prima facie case of obviousness with respect to the cited methods. Withdrawal of this ground of rejection is respectfully requested.

## **V. Claim Rejections – Double Patenting**

### **A. Renhowe**

Claims 1-6, 9-15, 16-38, 49-51, 53-58, and 67-71 stand rejected for alleged obviousness-type double-patenting (ODP) over claim 30 of Renhowe. In support of the rejection, the Office asserted that “Applicants have not provided any evidence that there are cancers that express PDGFR, c-Kit, or FLT-3 that do not also express VEGF.” Office Action, p. 21. Applicants respectfully traverse this rejection.

First, Applicants respectfully remind the Office that it carries the initial burden of establishing the obviousness of the present claims in view of claim 30 of Renhowe. Hence, in view of the amended claims, it is the Office which must establish that the present methods of treating, e.g., gastrointestinal stromal cancer, glioma, melanoma, bladder cancer and renal cancer, are obvious in view of claim 30. In so doing, the Office is reminded that for an ODP rejection, it may not rely on the disclosure of the specification of the cited reference. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992); see also MPEP § 804.

Second, in an ODP rejection as for a rejection under 35 USC 103(a), the Office must still provide a showing of a reasonable expectation of success for the claimed method. *See In re Braat*, 937 F.2d 589 (Fed. Cir. 1991) (the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 USC 103 obviousness determination). Nothing in claim 30 provides the skilled artisan with any reasonable expectation of success in a method of using the Renhowe compounds to treat the recited cancers. Treating a subject in need of a VEGF inhibitor is not the same as treating a subject having, e.g., melanoma.

Applicants respectfully submit that the Office has failed to establish a *prima facie* case of ODP over claim 30 of Renhowe. Accordingly, Applicants respectfully request withdrawal of the present ground of rejection.

**B. U.S. Pat. No. 7,470,709 by Barsanti (“Barsanti”) in view of Berge**

Claims 1-38, 49-51, 53-58, 67, and 69-71 stand rejected for alleged obviousness-type double-patenting (ODP) over claims 1-17 of Barsanti in view of Berge. As the claims of Barsanti do not mention the treatment of any one of the presently recited cancers (gastrointestinal stromal cancer, glioma, melanoma, bladder cancer and renal cancer), the Office has not established a prima facie case of ODP over Barsanti. The Office is again reminded that it has the burden to show why the claimed methods are obvious over the Barsanti claims which are directed to the treatment of hematologic cancers, acute myelogenous leukemia, ovarian carcinoma, breast carcinoma, lung cancer, colon cancer, prostate cancer, pituitary cancer, chronic myelogenous leukemia, or acute lymphoblastic leukemia cancers. As such a showing is presently lacking, Applicant respectfully requests withdrawal of this ground of rejection.

**CONCLUSION**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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